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[Full Title] Diabetes distress mediates the relationship between depressive symptoms and glycemic control among adults with type 2 diabetes: findings from a multi-site diabetes peer support intervention

[Short Running Title] Mediation effect of diabetes distress in type 2 diabetes

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[Novelty statement]

- Diabetes distress is positively associated with HbA1c and depressive symptoms among individuals with type 2 diabetes; diabetes distress has been suggested to mediate the relationship between depressive symptoms and HbA1c but this hypothesis has not been widely tested in diverse community samples.
- Using data from 5 collaborating US sites of peer support programs on diabetes self-management, this study found that diabetes distress mediated the relationship between depressive symptoms and HbA1c among individuals with type 2 diabetes from groups disproportionately affected by diabetes burdens.
- Interventions and services addressing diabetes distress may contribute to improving glycemic control and mental health.

[Ethics Statement]

The protocols of the projects on which these analyses were based were approved by the University of Alabama at Birmingham Institutional Review Board, the University of Michigan

Institutional Review Board, the Institutional Review Board at the University of California, San Francisco, and San Diego State University's Institutional Review Board.

[Data Availability]

Data is available on request due to privacy/ethical restrictions.

[Author Contributions]

Y.Q. and D.A.E. performed the literature search and wrote the manuscript. Y.Q. conducted the statistical analyses and designed data visualization. Y.Q., D.A.E., S.D.K., and E.B.F. contributed to conceptual model development, interpretation of data, and manuscript revision. G.X.A., A.L.C., M.H., M.M.S., T.S.T., D.H.T., and E.B.F. are principal investigators and made substantial contributions to the design and data collection of the five peer support programs in this study and the revision of this manuscript. All authors gave approval for the final version of the manuscript. E.B.F. is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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Abstract

Aims

Diabetes distress is positively associated with HbA1c and may mediate the relationship between depressive symptoms and HbA1c. This study examined these relationships in a geographically, socioeconomically, and ethnically diverse sample of adults with type 2 diabetes.

Methods

Using data from five US sites evaluating peer support for diabetes management (n=917), Structural Equation Modeling (SEM) examined whether diabetes distress (four items from Diabetes Distress Scale) mediated the relationship between depressive symptoms (PHQ-8) and HbA1c. Sites compared interventions of varying content and duration with control conditions. Time from Baseline Assessment to Final Assessment varied from six to 18 months. Site characteristics were controlled by entering site as a covariate along with age, sex, education, diabetes duration, insulin use, and intervention/control assignment.

Results

Depressive symptoms, diabetes distress, and HbA1c were all intercorrelated cross-sectionally and from Baseline to Final Assessment (rs from .10 to .57; *p*s<0.05). In SEM analyses, diabetes distress at Final Assessment mediated the relationship between Baseline depressive symptoms and HbA1c at Final Assessment (indirect effect: b=.031, *p*<0.001), controlling for Baseline HbA1c and covariates. Parallel analysis of whether depressive symptoms mediated the

relationship between Baseline diabetes distress and HbA1c at Final Assessment was not significant.

Conclusions

In this diverse sample, diabetes distress mediated the influence of depressive symptoms on HbA1c but the reverse, depressive symptoms mediating the effect of distress, was not found. These findings add to the evidence that diabetes distress is a worthy intervention target to improve clinical status and quality of life among individuals with type 2 diabetes.

Keywords: Type 2 diabetes, diabetes distress, depressive symptoms, glycemic control, HbA1c, peer support, self-management

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Introduction

Both depressive symptoms and diabetes distress complicate and contribute to the challenges for individuals living with type 2 diabetes. Globally, roughly 20% of people with diabetes are affected by depression [1]. Depressive symptoms among individuals with diabetes are associated with poorer self-management behaviors, poorer glycemic control, and more severe functional impairments [2]. Diabetes distress, "the negative emotional or affect experience resulting from the challenge of living with the demands of diabetes," [3] is reported by over one-third of individuals living with diabetes [4]. Studies have shown that the co-occurrence of elevated depressive symptoms and elevated diabetes distress is present in 5 to 15% of people living with diabetes [3]. Compared to depressive symptoms, diabetes distress is more predictive of diabetes self-management and clinical outcomes [5–7]. For example, studies found that elevated levels of diabetes distress were associated with lower levels of glycemic control, self-care behaviors, and quality of life, even after controlling for depression [2,3].

The relationships among depressive symptoms, diabetes distress, and glycemic control are complex and reciprocal [1]. Biologically, depression and diabetes distress may have a direct adverse effect on glycemic control via dysregulation of stress hormones [1]. Behaviorally, the association between diabetes distress and HbA1c may be attributable to psychological distress interfering with diabetes self-management [5]. That depression is closely related to glycemic control suggests treating depression may improve glycemic control. Evidence is mixed, however, regarding the impacts of treating depression on glycemic control, whether by cognitive or behavioral approaches [8] or with antidepressant medication [9].

Research suggests diabetes distress may mediate relationships between depressive symptoms and HbA1c, so that distress itself might be an intervention target for improving

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glycemic control [1,10,11]. Two cross-sectional studies among adults with diabetes in Germany and the Netherlands provided empirical evidence supporting the hypothesis that diabetes distress mediates the relationship between depressive symptoms and HbA1c [10,11]. However, little evidence exists as to whether this mediation hypothesis holds in longitudinal studies or among diverse populations, despite the evidence that diabetes distress may affect people of color and those of low socioeconomic status (SES) disproportionately [3,4,12].

The present study drew from combined samples of adults with type 2 diabetes from low income and varied marginalized ethnic populations in the United States (US) who participated in diabetes intervention studies of peer support (PS) conducted in diverse US settings [13–18]. The study used Structural Equation Modeling to examine 1) the diabetes distress mediation hypothesis, i.e., the direct effect of depressive symptoms on HbA1c and its indirect effect as mediated by diabetes distress, and 2) an alternative hypothesis that depressive symptoms mediate the relationship between diabetes distress and HbA1c.

Methods

Study design and participants

Our data come from a group of studies of PS interventions for diabetes management delivered in five different sites in the US [13–18]. Each of these interventions was funded by Peers for Progress, which focuses on promoting research and networking to encourage effective, feasible, scalable peer support for diabetes and other health problems [13,19,20]. The protocols of the individual projects were each approved by the institutional review boards of their corresponding institutions, the University of Alabama at Birmingham, the University of Michigan, the University of California, San Francisco, and San Diego State University. All participants provided informed consent. Information on each site's participants, settings, and study designs

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are summarized in Table 1. Although all sites shared the intervention goals of improving individuals' diabetes self-management and outcomes through PS, they did not follow a standardized study protocol: the PS activities, control groups, and program durations varied by sites (Table 1). As a result, the time from Baseline to Final Evaluation across the five sites ranged from 6 to 18 months. The results of the individual projects whose participants comprised the current sample have been published previously [13–18].

Each of the populations represented in this study's sample face barriers associated with racism and/or disadvantages in health care, economic or social factors or other areas. They include a predominantly African American community-based sample from rural Alabama [14], a community-based sample of low-income African Americans in Ann Arbor and Ypsilanti, Michigan [15], a clinic-based sample of Latina/o adults in southwestern Detroit, Michigan [16], an ethnically diverse clinic-based sample of low-income residents from San Francisco, California [17], and a clinic and community-based sample of low-income adults of Mexican heritage in rural Imperial County, California [18] (Table 1).

Across the five sites in the US, there were 1,280 participants. The current sample includes 917 participants who had complete data on the measures of interest detailed below, including 477 participants in usual care control conditions and 440 participants receiving usual care plus peer support interventions. The cases omitted because of incomplete data (n=363) did not differ from those retained (n = 917), as shown in Supplemental Materials Table S1.

Measures

HbA1c and measures of depressive symptoms and of diabetes distress were collected at Baseline Assessments after randomization to peer support or control conditions, and at Final

Assessment. As shown in Table 1, the time from Baseline to Final Assessment ranged from 6 to 18 months.

HbA1c reflects an individual's level of blood glucose over the previous three months (%). It was obtained directly via venipuncture or abstracted from qualified medical charts [14–18]. The measures of HbA1c varied by site. Table 1 provides detailed information of how HbA1c was obtained in each site.

Depressive symptoms were measured by the Patient Health Questionnaire (PHQ-8), a widely used scale among adults [21] including those with diabetes. This measure includes items addressing diverse experiences of depressed mood, e.g., the extent to which patients have "little interest or pleasure in doing things." Response options range from 0=not at all to 3=nearly every day. The total score of the eight items then reflects the frequency of depressive symptoms.

Diabetes distress was measured by four items drawn from the 17-item Diabetes Distress Scale [22] and used in previous analyses of peer support, diabetes distress, depression, and glycemic control [23]. Participants were asked the extent to which they have been "Feeling overwhelmed with the demands of living with diabetes," "Feeling that I am often failing with my diabetes routine," "Not feeling motivated to keep up my diabetes self-management," and "Feeling angry, scared, and/or depressed when I think about living with diabetes." For each item, response options range from 0=not a problem to 6=a very serious problem. The mean score of the four items was used to indicate the degree of diabetes distress [23].

Although the measures of depressive symptoms, diabetes distress, and HbA1c can be coded categorically, in the interest of sensitivity, they were each entered in analyses as continuous variables.

Statistical analyses

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Descriptive statistics calculated included means, standard deviation (SD), and frequencies of all measures mentioned above. HbA1c were reported both in IFCC units and DCCT units in descriptive analyses. Pearson Correlations examined relationships among continuous variables. Structural equation modeling (SEM) was used to investigate whether diabetes distress mediated the relationship between depressive symptoms at Baseline and HbA1c at Final Assessment. This is shown in Figure 1 as the pathway from baseline depressive symptoms to final diabetes distress (path a) to final HbA1c (path b). We used the delta method for testing mediation [24]. We also examined a second model with baseline depressive symptoms as the mediator between diabetes distress and final HbA1c (Figure S1). Covariates statistically controlled in the analyses include participants' age, sex, education, diabetes duration, insulin use, geographic site, group assignment (peer support intervention group vs control group), baseline levels of diabetes distress, and HbA1c (Figure 1). We included site as a control variable in order to control for potential measured and unmeasured site-level confounding factors, such as type of setting (e.g., community- or clinic-based), population demographics (e.g., racial composition), and study design (e.g., varying time between Baseline and Final Assessments) across sites.

All statistical analyses were conducted in R Studio Version 1.1.383. The package "psych" was used for descriptive statistics and the package "lavaan" was used for SEM.

Results

Descriptive and bivariate statistics

The sample demographic characteristics and the descriptive statistics of the clinical measures are presented in Table 2. This analytical sample was predominantly female (65.8%) and the average age was 57 years. At Baseline Assessment, 36.3% of the sample used insulin and on average, had lived with diabetes for 12 years (Table 2). Overall, at baseline, the sample

showed relatively poor glucose control with a mean HbA1c of 69 mmol/mol (8.5%). Mean score on diabetes distress was 2.39, lower than the cutoff for high diabetes distress of 3 [22]. Mean PHQ-8 score was 6.71, above the cut-point for mid depression and below that for moderate depression of 5 and 10, respectively [21].

Table 3 provides the results of the bivariate analyses. As expected, depressive symptoms, diabetes distress, and HbA1c were all intercorrelated. At both Baseline and Final Assessments, diabetes distress and depressive symptoms were highly correlated (rs = 0.56, 0.58 respectively, both $p < 0.001$) and each was moderately correlated with HbA1c (rs from 0.14 to 0.26, ps < 0.001). Additionally, age was negatively correlated with depressive symptoms and diabetes distress at both Baseline and Final Assessments (rs from -0.13 to -0.24, ps from 0.05 to 0.001). Education was positively correlated with diabetes distress at both Baseline and Final Assessments (rs = 0.09, 0.12, ps < 0.01, < 0.001 respectively), and duration of diabetes was positively correlated with HbA1c at both Baseline and Final Assessment (rs = 0.11, 0.08, ps < 0.001, < 0.05 respectively). Accordingly, age, education, and duration of diabetes were included as control variables in subsequent analyses.

Does diabetes distress mediate the relation between depressive symptoms and HbA1c?

The results of the SEM testing the hypothesized mediation by diabetes distress are presented in Figure 2. Among all participants in the sample (n=917), the model fit was good (X^2 =890.121, df = 27, $p < 0.001$; RMSEA (root mean square error of approximation) = 0.027; CFI (comparative fit index) = 0.999, TLI (Tucker Lewis Index) = 0.980). Although the Chi-square statistic was significant, the model was acceptable since it is difficult to obtain a nonsignificant Chi-square value with large samples [25] and the other criteria indicated good model fit.

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Higher depressive symptoms at baseline were associated with higher diabetes distress at Final Assessment (path a: b=0.209, $p < 0.001$), after controlling for baseline diabetes distress and other covariates (age, sex, education, diabetes duration, insulin use, geographic site, and group assignment). At Final Assessment, higher diabetes distress was associated with higher HbA1c (path b: b=0.150, $p < 0.001$), after controlling for baseline HbA1c and other covariates. In the mediation analyses, there was a significant indirect effect of depressive symptoms on HbA1c through diabetes distress (a*b: b=0.031, $p < 0.001$).

Do depressive symptoms mediate the relation between diabetes distress and HbA1c?

The results of the SEM testing the possibility that depressive symptoms mediate the relationship between diabetes distress and HbA1c are presented in Supplement Figure 2. As with the previous SEM, the model fit was good (RMSEA = 0.025; CFI = 0.999, TLI = 0.983) although, with the large sample, Chi-square was again significant (X^2 =901.051, df = 27, $p <$ 0.001).

Diabetes distress at Baseline Assessment was not significantly associated with depressive symptoms at Final Assessment (path a': b=0.035, p=0.275). However, higher depressive symptoms at Final Assessment were associated with higher HbA1c at Final Assessment (path b': b= 0.085, p=0.003), after controlling for baseline HbA1c and other covariates. In the analysis of mediation, an indirect effect of diabetes distress on HbA1c through depressive symptoms, was not significant (a'*b': b= 0.003, p=0.306). Thus, the alternative hypothesis that depressive symptoms mediate the relationship between diabetes distress and HbA1c was not supported.

Discussion

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In a geographically and ethnically diverse sample of low-income and both rural and urban-residing individuals with type 2 diabetes, those with more severe depressive symptoms reported higher levels of diabetes distress and HbA1c. The SEM analyses found a) diabetes distress mediated the relationship between baseline depressive symptoms and HbA1c at Final Assessment, but b) depressive symptoms did not mediate the relationship between diabetes distress and HbA1c.

Studies have shown that although both depressive symptoms and diabetes distress are related to glucose control, diabetes distress is more closely related to patients' diabetes self-management and clinical outcomes [5–7]. Beyond differences in the strength of relationships, our findings suggest that diabetes distress may be an important link between more generalized symptoms of depression and HbA1c among individuals with type 2 diabetes. General depressive symptoms may influence the negative emotional experience with diabetes resulting from the complex self-management routine, fear of complications, and lack of social support, etc., and these stressors may further lead to poorer self-management and glycemic control. This mediation effect of diabetes distress in the current sample is also consistent with previous cross-sectional studies in European samples that were predominantly white with relatively high education [10,11].

Although it is important to treat depression in adults with diabetes, interventions focusing solely on reducing depression have not been reliably effective in improving clinical status among those with diabetes [7]. The present findings add to the evidence that interventions targeting the emotional stress of managing diabetes are beneficial [26]. Along these lines, reductions in diabetes distress were associated with improved glycemic control in one study among rural African American women [27].

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Previous behavioral interventions facilitated by trained nurses or mental health specialists have shown positive impacts on diabetes outcomes [7]. Using data from the site in rural Alabama, Safford and colleagues found significant group differences favoring peer support relative to usual care in changes in diabetes distress, quality of life, BMI, and systolic BP, after controlling for clustering and education [14]. Other peer support interventions for those with diabetes also have shown benefits on combinations of psychosocial and metabolic outcomes [28,29].

African Americans and Latina/o individuals in the US experience disproportionate prevalence of diabetes and its complications, as well as everyday stressors that can lead to more difficulties in diabetes management, elevated diabetes distress, and poor glycemic control [30]. Pooling data from the five US sites enabled examination of diabetes distress and glycemic control among a sample of predominantly African Americans or Latina/o individuals, burdened by racism and associated inequities as well as diverse educational and economic disadvantages, and thereby generally representative of those experiencing disproportionate diabetes burden.

This paper focused on and found evidence for the diabetes distress mediation hypothesis. Nevertheless, it is important to recognize the complexity of the relationships among depressive symptoms, diabetes distress, and glycemic control and the scientific values of examining other potential pathways, such as the possible impacts of glycemic control on diabetes distress and depressive symptoms. Moreover, future research may explore other mediators between depressive symptoms and glycemic control, such as self-management behaviors, simultaneously with diabetes distress, to further illuminate the mechanisms of how depressive symptoms influence glycemic control.

Strengths and Limitations

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Compared to previous cross-sectional mediation analyses [10,11], our study benefits from the larger sample size from five collaborating sites which increased its statistical power and sample diversity. By using SEM and data from two time points when testing the mediation effect of diabetes distress, we were able to establish temporality between depressive symptoms and diabetes distress, as well as to adjust for the influence of baseline levels of diabetes distress and HbA1c on their final levels. Our ability to make stronger causal claims based on current mediation analyses is limited by the lack of a third datapoint.

Our study has several limitations. First, our analyses were based on a sample of participants with mean distress below the cutoff for high diabetes distress and PHQ-8 depression between the cutoffs for mild and moderate depression. Our findings may not be generalizable to other samples with predominantly higher or lower levels of diabetes distress and/or depressive symptoms. An additional limitation is different sites obtained HbA1c in different ways.

Third, our analyses did not account directly for potential influences of participants' income and ethnicity as they may contribute to diabetes distress, depressive symptoms and/or glucose control. Not all of the five sites obtained detailed measures of income and ethnicity. Considering potential confounding of participants' SES, we included education as a covariate in our analyses. Ethnicity was highly homogenous within each site [23]. By controlling for geographic site, we sought to rule out site-level confounding in the analyses. However, this approach may limit our understandings of how specific site-level factors may influence the conclusion.

Finally, the majority of excluded cases were due to missingness in key variables at the Final Assessment. We cannot rule out the possibility that missingness was not random. For example, participants with fewer challenges in their diabetes self-management may have been more like to drop out from the study because of lower motivation to participate and thus their

measures at Final Assessment were missing. Using listwise deletion of missing variables, 71.6% of participants with baseline data (917 of 1,280) were included in the analyses. Although the exclusion of 28.4% of participants may have introduced selection bias, we found only a marginally significant difference between those included and not included for duration of diabetes (mean = 12.05 for those included, 10.72 years for those not included, p=0.05) while for all other such comparisons, $p > 0.10$ (Table S1). Accordingly, diabetes duration was among those variables controlled in the SEM analyses. Additionally, the percentage of missing data varied significantly by site, from 14.0% to 29.2%. The inclusion of site as a control variable in the analyses adjusted for all potential site-level confounders.

Conclusion

In this geographically, socioeconomically, and ethnically diverse sample of adults with type 2 diabetes, diabetes distress mediated the effect of depressive symptoms on HbA1c but the reverse, depressive symptoms mediating the effect of distress, was not found. More severe depressive symptoms were associated with a higher level of distress related to diabetes, which in turn was associated with poorer glycemic control. These findings suggest that interventions addressing diabetes distress and determinants of it in diabetes burdens and diabetes management may contribute to both improved glycemic control and quality of life.

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Table 1. Descriptions of study sites

Site	Intervention participants and Settings	Study design	Description of peer support intervention	Length of Final Assessment*
Rural Alabama	African Americans; Community based	Cluster randomized trial; Intervention group: Brief education at Baseline + 10-month peer-coaching intervention; Control group: brief education alone	Weekly telephone interactions with paired peer coaches for 8 weeks, then monthly for 8 months.	10 months
Ann Arbor/Ypsilanti, Michigan	Low-income African Americans; Community based	Randomized controlled trial; Intervention group: 3-month diabetes self-management education (DSME) + 12-month diabetes self-management support delivered by peer leaders (PL); Control group: DSME alone	Weekly group sessions and Final Assessment telephone contacts.	15 months
Southwest Detroit, Michigan	Low income, Latinas/Latinos of Mexican origin; Clinic based	Randomized controlled trial; PL group (intervention): 6-month DSME program led by community health workers (CHWs) + 12-month PL emotional and behavioral support; CHW group: 6-month DSME program led by CHW + monthly telephone outreach initiated by CHW	Weekly group sessions and Final Assessment telephone contacts.	18 months
San Francisco, California	Low income, ethnically diverse (over half sample were Latinos or African Americans); Clinic based	Randomized controlled trial; Intervention group: 6-month clinic-based peer health coaching; Control group: usual care, including access to a nutritionist and diabetes educator through referral from primary care clinician.	One-on-one peer coaching includes telephone contact at least twice a month and 2 or more in-person contacts.	6 months
Rural Imperial County, California	Low-income, Mexican heritage (majority were foreign born); Clinic and community based	Randomized controlled trial; Intervention group: 12-month support delivered by peer leader; Control group: usual care, involving primary and specialty care and access to diabetes education classes.	8 contacts in the first 6 months and additional contacts during the subsequent 6 months.	12 months

Note: * Several sites conducted multiple assessments during their study period. In this paper, we pooled the data from their Final Assessments, which were conducted after interventions were completed in all sites.

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Table 2. Analytical sample characteristics (n=917)

	Mean (SD)	N (%)
Baseline diabetes distress	2.39 (1.32)	
Baseline depressive symptoms	6.71 (5.59)	
Baseline HbA1c (%)	8.54 (2.03)	
Diabetes distress at Final Assessment	2.04 (1.17)	
Depressive symptoms at Final Assessment	5.80 (5.54)	
HbA1c at Final Assessment (%)	8.36 (2.16)	
Age (years)	57.26 (11.85)	
Sex		
Female		603 (65.8%)
Male		314 (34.2%)
Education (years)	10.86 (4.28)	
Duration of diabetes (years)	12.05 (10.63)	
Insulin use		
Yes		333 (36.3%)
No		584 (63.7%)
Geographic site		
Imperial County, CA		264 (28.8%)
San Francisco, CA		216 (23.6%)
Birmingham, AB		318 (34.7%)
Detroit, MI		65 (7.1%)
Ypsilanti, MI		54 (5.9%)
Group assignment		
Peer support intervention		440 (48.0%)
Control group		477 (52.0%)

Note: age, sex, education, duration of diabetes, and insulin use were obtained at Baseline Assessment.

Table 3. Correlation matrix of key measures

	Education	Duration of diabetes	Baseline Diabetes Distress	Baseline Depressive symptoms	Baseline HbA1c	Diabetes Distress at Final Assessment	Depressive symptoms at Final Assessment	HbA1c at Final Assessment
Age	-0.17***	0.36***	-0.24***	-0.14***	-0.23***	-0.17***	-0.13*	-0.25***
Education		-0.15***	0.09**	0.04	0.07*	0.12***	0.01	0.06
Duration of diabetes			-0.08*	-0.05	0.11***	-0.06	-0.02	0.08*
Baseline Diabetes Distress				0.56***	0.23***	0.53***	0.38***	0.17***
Baseline Depressive symptoms					0.14***	0.45***	0.57***	0.10**
Baseline HbA1c						0.21***	0.17***	0.59***
Diabetes Distress at Final Assessment							0.58***	0.26***
Depressive symptoms at Final Assessment								0.20***

Note: *$p < 0.05$; **$p < 0.01$; ***$p < 0.001$

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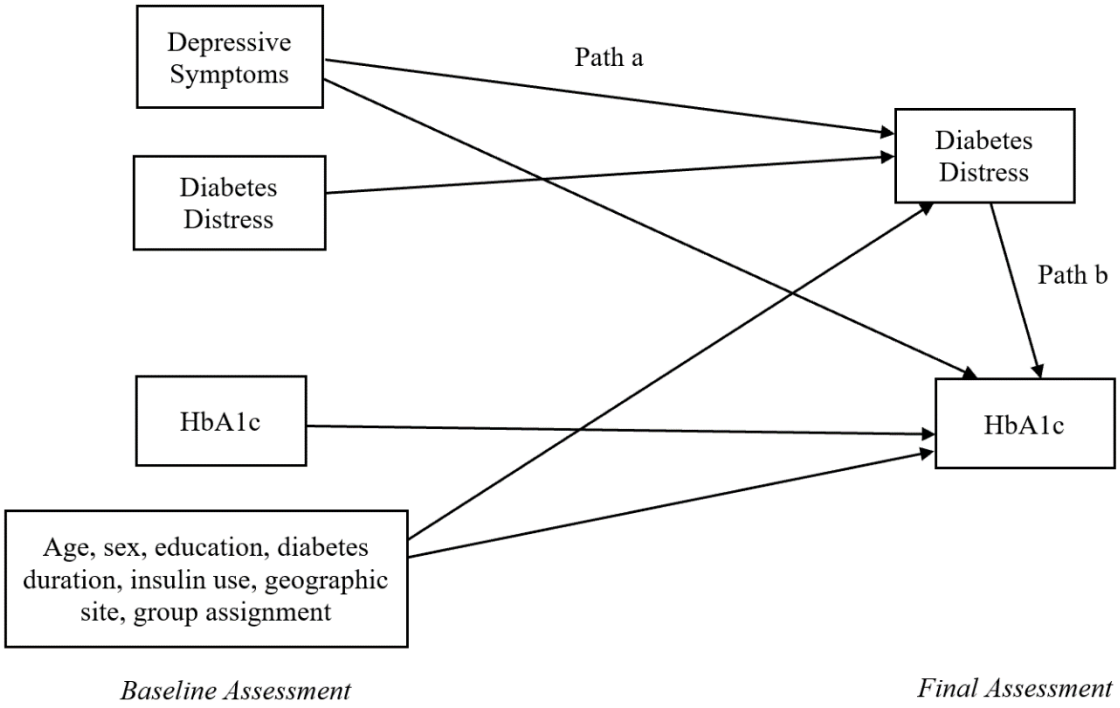


Figure 1. Proposed Structured Equation Model.

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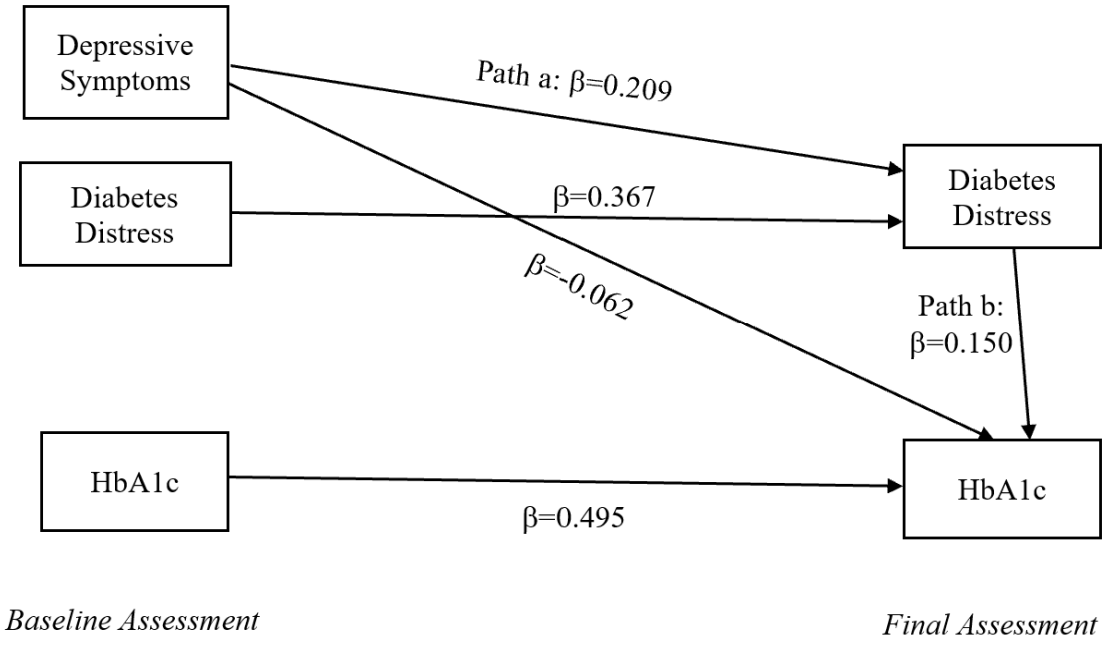


Figure 2. Results from the Proposed Structured Equation Model. Significant pathways from Figure 1 are shown as solid lines. All relationship controlled for age, sex, education, insulin use, diabetes duration, geographic site, and group assignment (estimates not shown for simplicity). X2=890.121, df=27, $p<0.001$; RMSEA=0.027; CFI=0.999, TLI=0.980.

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Table 1. Descriptions of study sites

Site	Intervention participants and Settings	Study design	Description of peer support intervention	Length of Final Assessment*
Rural Alabama	African Americans; Community based	Cluster randomized trial; Intervention group: Brief education at Baseline + 10-month peer-coaching intervention; Control group: brief education alone	Weekly telephone interactions with paired peer coaches for 8 weeks, then monthly for 8 months.	10 months
Ann Arbor/Ypsilanti, Michigan	Low-income African Americans; Community based	Randomized controlled trial; Intervention group: 3-month diabetes self-management education (DSME) + 12-month diabetes self-management support delivered by peer leaders (PL); Control group: DSME alone	Weekly group sessions and Final Assessment telephone contacts.	15 months
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Rural Imperial County, California	Low-income, Mexican heritage (majority were foreign born); Clinic and community based	Randomized controlled trial; Intervention group: 12-month support delivered by peer leader; Control group: usual care, involving primary and specialty care and access to diabetes education classes.	8 contacts in the first 6 months and additional contacts during the subsequent 6 months.	12 months

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